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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,645	WOZNEY ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1- 52* is/are pending in the application.

4a) Of the above claim(s) *3,5,9,14-17,20-26,28,30,32-35 and 37-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-8,10-13,18,19,27,29,31 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 December 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, the polynucleotides of SEQ ID NO: 1, in the reply filed on 9 November 2004 is acknowledged. Claims 1- 52 are pending in this office action. Claims 1, 2, 4, 6-8, 10-13, 18, 19, 27, 29, 31, and 36 are under examination as they pertain to SEQ ID NO: 1. Claims 3, 5, 9, 14-17, 20-26, 28, 30, 32-35, and 37-52 are withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The disclosure is objected to because of the following informalities: There is a blank space on p. 15. In addition, there are sequences on pp. 27 and 28 that require sequence identfiers.

Appropriate correction is required.

Claim Objections

3. Claims 1, 2, 4, 6-8, 10-13, 18, 19, 27, 29, and 36 are objected to because of the following informalities: They encompass non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 2, 4, 6-8, 10-13, 18, 19, 27, 29, 31, and 36 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific, or well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The specification fails to provide objective evidence of any activity for the encoded protein. All that is provided is that statement that it is a BMP receptor, and a description of assays that can be performed (pp. 36-41). Further, the specification does not disclose any activities, diseases or conditions known to be associated with the encoded protein. The specification states only that BMPs are able to promote wound healing and tissue repair. While it is stated that cells expressing the receptor exhibit increased binding to BMP-2 and BMP-4, there is no objective evidence to indicate that the receptor in fact binds BMP-2 or BMP-4 and no evidence as to what the consequences of this binding would be. Thus, further research is required to identify a use for the claimed receptor. Further, identification of molecules that regulate the expression of this protein, and screens for molecules are related to this protein (pp. 12-13) are useful only in research to determine the function of the protein itself: there is no "specific benefit in currently available form" to be derived from such studies. Applicant thus does not identify or confirm a "real world" context of use; clearly further research would be required to identify a disease or function associated with this protein and thus endow the encoding polynucleotides with a utility. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the

search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. See also the Revised Interim Utility Guidelines available at www.uspto.gov.

The claimed invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. Applicant states (p. 35) that the protein is homologous to the TGF-β type II receptor and the activin types II and IIb receptors, as well as daf-1. Identifying a protein as having a limited homology to TGF-β family receptors does not endow it with a well-established utility; these proteins bind three different agents. There is therefore no specific, substantial, or credible utility that is well-known, apparent, or implied by the relationship of the instant polynucleotide to the polynucleotides encoding these factors.

6. Claims 6-8 and 11 are additionally rejected under 35 U.S.C. 101 because they encompass non-statutory material.

Because they do not require that the host cells be isolated they encompass humans comprising these cells, such as gene therapy patients, which Applicant does not intend to encompass.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 2, 4, 6-8, 10-13, 18, 19, 27, 29, 31, and 36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9. Claims 1, 2, 4, 6-8, 10-13, 18, 19, 27, 29, and 36 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, were it enabling for nucleic acids encoding SEQ ID NO: 2, would still not reasonably provide enablement for the genus of nucleic acids identified by hybridization, with only the requirement that they bind a BMP or for the genus of nucleic acids encoding all BMP receptors, or for allelic variants.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant has described the polynucleotide of SEQ ID NO: 1. However, applicant has not described the characteristics of this nucleic acid sequence so that one of skill in the art could predictably identify other sequences encoding proteins with similar structural and functional features. Applicant has not described the properties or characteristics of the sequence that are required to encode a functional protein. Thus, the essential characteristics of nucleic acids encoding Cfk1-23a proteins are not described. Since there is no requirement that any particular

BMP be bound, the functional limitation provides no direction as to the structure or characteristics of the claimed genus.

Claims 1, 6, 18, 27, 29, and 36 are more broadly drawn and encompass all nucleic acids encoding BMP receptors. Applicant has described three nucleic acids sequences. However, Applicant has not described the common characteristics of these three nucleic acid sequences so that one of skill in the art could predictably identify other sequences encoding BMP receptors. No conserved regions important for the particular binding characteristics or for signaling are described. Thus, the essential characteristics of nucleic acids encoding BMP receptors are not described.

Claim 10 encompasses allelic variants. There is no guidance as to the structure of these variants and their structure cannot be predicted from the identification of a single naturally occurring molecule.

The claims thus encompass nucleic acids potentially widely divergent in structure and function, with no guidance as to the defining characteristics. While recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in BMP receptor function or specifically in Cfk1-23a function, in order to make and use the invention commensurate with the scope of the claims without undue experimentation.

10. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim is drawn to the sequence of a plasmid. Applicant's referral to the deposit of CFK 1-23A on page 4 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that a deposit been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited material is required.

11. Claims 1, 2, 4, 6-8, 10-13, 18, 19, 27, 29, and 36 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to a genus, i.e. polynucleotides identified by hybridization. Claims 1, 6, 18, 27, 29, and 36 encompass "BMP receptors" in general. Claim 10 further

encompass allelic variants. Applicant has disclosed one species, the polynucleotide of SEQ ID NO: 1, but has not disclosed sufficient species for the broad genus of any polynucleotide encoding SEQ ID NO: 2 and related sequences.

The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from other BMP receptors are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed: there is no guidance in the prior art as to what the defining characteristics of Cfk1-23a might be. Thus, no identifying characteristics or properties of the instant polynucleotides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of SEQ ID NO:1 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claims 1, 6, 18, 27, 29, and 36 are still broader in scope, since they are drawn to "BMP receptors" and thus to sequences that vary substantially in length and also in composition. The instant disclosure of three nucleic acids thus does not adequately describe the scope of the claimed genus. As stated above, Applicant has not disclosed the common characteristics requied for BMP binding and for function. Thus, the essential characteristics of nucleic acids encoding BMP receptors are not described.

Claim 10 encompasses allelic variants. Applicant has not set forth the sequences of those variants, which are particular molecules that exist in nature but whose structure is not known or predictable based on Applicant's disclosed sequence. Thus one of skill in the art would not conclude that Applicant was in possession of the claimed genus of allelic variants.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 4 are drawn to molecules identified by stringent hybridization. However, Applicant has not defined these conditions. Only examples are provided. Thus, one of skill in

the art would not be able to determine what conditions, and thus what nucleic acids, Applicant intended the claims to encompass.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
24 January 2005

JANET ANDRES
PRIMARY EXAMINER